RECEIVED AT DRUG SAFETY SURVEILLANCE
27-FEB-1998-0461

McNEIL
FC

Individual Safety Report
3037722-3-00

rv FDA on 11/16/93

FDA use only

Page ____ of ____

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
Case #4 in confidence	35 yrs or Date of birth:	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (X) death 10/28/93 (mo/day/yr)
- ( ) life-threatening
- ( ) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event	4. Date of this report
10/24/93 (mo/day/yr)	02/16/98 (mo/day/yr)

5. Describe event or problem

Reports of 19 cases complied by attorney & sent to FDA;Agency forwarded these reports to McNeil upon request to Docket No.77N-094W,Ref.94,Vol.6 of 7. Of the 19 cases,11 were previously submitted to FDA by McNeil (Mfr.# 0158783A,0171537A, 0284020A, 0325998A, 0374114A, 0495613A, 0505064A, 0505223A, 0505252A, 0599479A,0673820A). Case document #4 indicates 35 yoF w/several days hx of flu symptoms including N&V,myalgia, arthralgia,was found unresponsive(10/24/93) & brought to ER. Pt seen by MD 2 days prior;ZANTAC & PHENERGAN prescribed. In ER,pt was icteric & diaphoretic, w/Temp=102.4,w/decorticate posturing, several ecchymoses & lg liver palpable. Over 48 hrs,deteriorated neurologically,w/pupils F&D, Sz(CONVULSION) & CT Scan showing diffuse edema.Temp rose to 106 F, B/P= 98/35. Pt died(DEATH)10/28/93. D/C Dx: severe centrilobular hepatic NECROSIS,CEREBRAL EDEMA, SUBARACHNOID HEMORRHAGE,adrenal gland necrosis,HEPATIC COMA/encephalopathy,acute renal insuff, prerenal azotemia (ACUTE KIDNEY FAILURE), viral syndrome, SZ D/O, poss.DIC & acetaminophen toxicity/OVERDOSE.

6. Relevant tests/laboratory data, including dates

10/24/93 glucose=355 mG/dL, T BIL=9.1mG/dL, D BIL=6.1mG/dL, I BIL= 3.0mG/dL, AlkPhos=204U/L, GGTP=387U/L, SGOT=5360U/L, Temp=102.4 F, pH=7.55, PCO=28.7, BUN=62, Creatnine=1.5, AMY= 296, Total protein=5.2, NH3=267, SGPT=8920 (See Sect.B.7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

no definite hx of alcohol intake; previously diagnosed w/ viral syndrome & gastritis

Cont'Sect.B.6: Coma Panel (serum) acetone=less than 5.0 mg/dL, acetaminophen 60.3 mg/L; Coma Panel (urine) none detected for drugs; 10/27/98 EEG was flatline; Serologic studies for Hepatitis A,B,C were negative; (See Sect.C.10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unknown TYLENOL® acetaminophen product

#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 unknown dose, po	#1 unknown date or duration
#2	#2

4. Diagnosis for use (indication)

#1 fever and chills

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

ZANTAC® & PHENERGAN®

Cont'Sect.B.7: Liver pathology: extensive centrilobular necrosis w/o evidence of hepatitis

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number

215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- ( ) literature
- ( ) consumer
- ( ) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- (X) other: attorney

4. Date received by manufacturer (mo/day/yr) 12/31/97

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) Initial ( ) follow-up #

8. Adverse event term(s)

DEATH
EDEMA BRAIN
COMA HEPATIC
CONVULSION
NECROSIS
HEM SUBARACHNOI
KIDNEY FAIL ACU
OVERDOSE

9. Mfr. report number

0934002A

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes (X) No	attorney	(X) Yes ( ) No ( ) Unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or